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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,800	01/17/2006	William Levine	4110-42	4537

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EXAMINER	
CHEN, CATHERYNE	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,800	LEVINE ET AL.	
	Examiner	Art Unit	
	CATHERYNE CHEN	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Currently, Claims 1-3, 5-16 are pending. Claims 1-3, 5-16 are examined on the merits. Claim 4 is canceled.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on Dec. 18, 2008 has been entered.

Election/Restrictions

Applicant's election without traverse of Sambucus nigra, Centella asiatica, Enchinacea purpurea in the reply filed on Dec. 15, 2006 is acknowledged.

Response to Arguments

Applicant's arguments with respect to claims 1-3, 5-7 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

Claim 13 is objected to because of the following informalities:

A claim needs to be a sentence. The punctuation period is missing.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 8-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathiowitz et al. (US 6217908 b1)), 1001herbs (http://www.1001herbs.com/elderberrycombo/), Holistic-online (http://www.holistic-online.com/herbal-med/_Herbs/h18.htm), Ceschel et al. (2001, Drug Delivery, 8, 161-171).

Mathiowitz et al. teaches composition as drug delivery systems in the area of gastrointestinal, vaginal, and respiratory drug delivery, administration via nasal or oral passage (column 1, lines 11-17). Controlled release systems for drug delivery by adhering the lining of the appropriate viscus, its content can be delivered to the target tissues as a function of proximity and duration of contact (column 1, lines 21-29). Mucoadhesion improves bioavailability (column 1, lines 53-58). Bioadhesive polymers in the form of or as a coating on microcapsules containing drugs or bioactive substance (column 3, lines 56-57). Two classes of polymers are useful for its bioadhesive properties are polyacrylic acid (column 7, lines 22-25), natural polymer is polyvinylpyrrolidone and synthetically modified natural polymer is hydroxypropyl cellulose (column 7, lines 51, 57). Lectins from Sambucus nigra can be covalently attached to microspheres to render them target specific to the mucin and mucosal cell layer (column 11, lines 1-15). The microspheres are administered in suspension to mucosal membranes via the nose, mouth, rectum or vagina with pharmaceutically acceptable carriers for oral administration that are compatible with the polymeric material (column 14, lines 43-46). The non-adhesive side would be intrinsically taught because the inside of the shell would be in contact with the dispersing agent; thus, the dispersing agent would be the non-adhesive side. However, it does not teach Echinacea purpurea, Centella asiatica, lactose, contact time.

1001herbs teaches Echinacea purpurea and elderberry or Sambucus nigra at 394 mg for use in boosting immune system to prevent cold-and-flu (paragraph 1).

Holistic-online teaches Centella asiatica or gotu kola for treating fever, immune system strengthening (page 2, Useful for) and infections (page 2, paragraph 2).

Ceschel et al. teaches a variety of drugs can be absorbed by buccal, sublingual or gingival mucosa and local treatment of inflammatory disease at the site of administration and the degrees of systemic side effects can be minimized (page 161, right column, paragraph 1). The formulation is for a mucoadhesive, specifically buccal, administration likes lozenges, troches, gels, oral rinse or mouthwash for delivery of drugs through the mucosa of the oral cavity (page 161, paragraph 2). Bioadhesive polymers-copolymers can control drug delivery by localizing in a specific surface which is able to absorb drugs, leading to enhancement of bioavailability, prolonging residence time and ensuring optimal contact with the absorbing surface and have gelling properties that can be exploited to obtain a control of drug release (page 162, left column, lines 2-9). Composition for tablets with lactose at amounts of 42.17, 37.17, 32.17%, mucoadhesive PVP (polyvinylpyrrolidone) PK30 at amounts of 10, 20, 30% (page 162, Table 1). Table 8 shows tablet detachment or disgregation time at 1 hour 24 minutes. The concentration of mucoadhesive polymer need to be more than 10% to avoid tablet detachment and that disgregation time increased with an increase of mucoadhesive concentration (page 170, paragraph 1).

Mathiowitz et al. teaches composition as drug delivery systems with lectin, a plant extract from Sambucus nigra. The drug delivery of Mathiowitz et al. can be used to deliver the 1001herbs taught Echinacea purpurea and elderberry or Sambucus nigra at 394 mg for use in boosting immune system (paragraph 1) and Holistic-online taught

Centella asiatica or gotu kola for treating fever, immune system strengthening (page 2, Useful for) and infections (page 2, paragraph 2). Thus, an artisan of ordinary skill would reasonably expect that ingredients that can boost immune system could be used as the type composition for delivery taught by the references. This reasonable expectation of success would motivate the artisan to use Sambucus nigra, Centella asiatica and Echinacea purpurea as the muco-adhesive drug in the reference composition. Thus, using Sambucus nigra, Centella asiatica and Echinacea purpurea as the muco-adhesive drug is considered an obvious modification of the references.

Mathiowitz et al. teaches bioadhesive polymers in the form of or as a coating on microcapsules containing drugs or bioactive substance (column 3, lines 56-57). Ceschel et al. teaches mucoadhesive,specifically buccal, administration likes lozenges, troches, gels, oral rinse or mouthwash for delivery of drugs through the mucosa of the oral cavity (page 161, paragraph 2) and composition for tablets with lactose at amounts of 42.17, 37.17, 32.17%, mucoadhesive PVP (polyvinylpyrrolidone) PK30 at amounts of 10, 20, 30% (page 162, Table 1) with Table 8 showing tablet detachment or disgregation time at 1 hour 24 minutes. Thus, it would be obvious to add lactose into mucoadhesive formulation, such as that taught by Ceschel et al. An artisan of ordinary skill would clearly expect that the bioadhesive tablets taught by Ceschel et al. would function successfully to administer the bioadhesive microcapsules taught by Mathiowtiz et al. This reasonable expectation of success would motivate the artisan to modify Mathiowtiz et al. to include lactose as an effective means to administer the bioadhesive formulation.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant. However, the references do teach the composition for mucoadhesive compositions. Ceschel et al. teaches composition for tablets with lactose at amounts of 42.17, 37.17, 32.17%, mucoadhesive PVP (polyvinylpyrrolidone) PK30 at amounts of 10, 20, 30% (page 162, Table 1). Table 8 shows tablet detachment or disgregation time at 1 hour 24 minutes. The concentration of mucoadhesive polymer need to be more than 10% to avoid tablet detachment and that disgregation time increased with an increase of mucoadhesive concentration (page 170, paragraph 1). The amount of a specific ingredient in a composition that is used for a particular purpose (the composition itself or that particular ingredient) is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 8-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-11, 13, 20, 22, 24-29, 34-35, 37, 39-44, 50, 52-55, 58-60, 62, 68 of copending Application No. 10/478718, which is allowed but not published as a patent yet. Although the conflicting claims are not identical, they are not patentably distinct from each other because the therapeutic composition containing the plant species Sambucus nigra, Centella asiatica, and Echinicea purpurea for treatment of mucosal lesions of the oral or anal mucosa are found both in the Applicant's claims and the Application 10/478718.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

/Michael V. Meller/

Primary Examiner, Art Unit 1655